

Serial No. 10/672,695
Filed: 4/11/2002
Inventor: Boyle, et al.
Attorney Docket: 6006-107
Customer No. 29,335

REMARKS

In response to the Examiner's 42-way restriction requirement, and as best understood, Applicant provisionally elects to prosecute Species 2 as shown in Figure 4, with traverse. Species 2, as shown in Figure 4, depicts the combination of a support structure (e.g., "stent") and a microporous covering (e.g., "graft"). Applicant submits that each of pending Claims 1-35 are directed to the elected Species, and, therefore, that no claims need be withdrawn or cancelled in response to the restriction requirement.

Applicant traverses on the basis that the Examiner has not satisfied the burden imposed under MPEP §803 of making a *prima facie* showing that searching the identified species and sub-species imposes a serious burden on the Examiner. For the Examiner to make a *prima facie* showing, the Examiner must demonstrate by either an appropriate explanation of separate classification or separate status in the art, or a different field of search as defined in MPEP § 808.02. Only after such a *prima facie* showing made, is Applicant required to rebut by making appropriate showings or proffering appropriate evidence. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant. Applicant respectfully submits that the Examiner's Restriction Requirement is improvidently issued and fails to comport with the requisite *prima facie* showing required by MPEP §803. The Examiner has failed to establish that searching the purported species and sub-species imposes a serious burden upon the Examiner. The Examiner has not alleged or argued that the purported species and sub-species have attached separate classification, separate status in the art or are in a different filed of search. Accordingly, the requirement for Applicant to elect a species and sub-species has been improperly made.

MPEP §806.04(a) – (i) govern restriction practice relating to claims to genus-species. In the present case, the Species 1-24 and sub-species 25-42 are each related to one another under the Applicant's disclosure and are, therefore, permissible as combinations and sub-combinations within the context of a single application pursuant to MPEP §806.04(b). Specifically, species 3-23 (Figures 6-23) are directed toward different sizes, shapes and patterns of the openings in the "microporous metal thin film" claimed in

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Claim 1, 18 and 29, and exemplify different "uniform pattern of openings" as claimed in dependent Claims 9 and 26 or "regular pattern of openings" as claimed in Claim 34. Furthermore, with respect to species 1, and 24-41 (Figures 1, 5, and 27-40) alternate stent pattern geometries are depicted. Each of the alternate stent pattern geometries are generically claimed as "a structural support element" (Claims 1, 18, and 29). Even its most specific context, as claimed in Claim 29, each of the species has the common elements of "at least a pair of undulating cylindrical elements having a plurality of peaks and valleys and interconnecting members joining adjacent cylindrical elements at either the peaks or the valleys and having at least one projection extending longitudinally [from] a terminal cylindrical element...."

Within the group of Species 2-23, the sole distinction between the purported species is the shape and pattern of the openings. In several instances, the Examiner has identified as separate species, different views of the same opening pattern. For example, Figure 7 (Species 4) is a diagram depicting the tension and compression effect of the pattern of Figure 8 (Species 5). In other instances, the Examiner has identified different species having the same slot pattern, but with a different axial orientation relative to the longitudinal axis of the device, e.g., Figure 9 (Species 6) having a staggered slot pattern oriented perpendicular to the longitudinal axis of the device, Figure 10 (Species 7), having the same staggered slot pattern oriented helical relative to the longitudinal axis of the device and Figure 11 (Species 8), having the same staggered slot pattern oriented parallel with the longitudinal axis of the device. The same relationship exists between the slot pattern in Figures 12 (Species 9) and 14 (Species 11) which are the same opening pattern having a perpendicular and parallel orientations relative to the longitudinal axis of the device, respectively. Additionally, Figure 13 (Species 10) depicts a pattern of openings which is highly similar to that depicted in Figure 9 (Species 6), with the exception that there are different slot lengths between slots 142 and 146 (Figure 13) whereas in Figure 9, the slots 92 are depicted with common lengths. Figures 17 (Species 14), 18 (Species 15), 19 (Species 16), 20 (Species 17), 23 (Species 20), 24 (Species 21), 22 (Species 22), 23 (Species 23) and 41 (Species 42) depict alternative embodiments of

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different geometries of the microporous openings in the claimed "microporous metal thin film" common to each independent claim 1, 18 and 29, and, therefore, simply represent combinations and sub-combinations which are permissible in a single application within the ambit of MPEP §806.04(b).

Within the group of sub-species 25-42, there are alternative geometries of the structural support member. Thus structural support member is an element which is generically claimed in each of independent claims 1, 18 and 29. Each of the different geometries embodied in the purported species have the generically claimed common elements, namely "at least a pair of cylindrical elements and interconnecting members joining cylindrical elements". The sub-species identified by the Examiner differ only in minor respects, e.g., the length of the interconnecting member as depicted in Figures 28A and 28B, which the Examiner has classified as distinct sub-species 28 and 29, respectively, or as to the number of interconnecting members as exemplified in Figures 29 and 30, which the Examiner has classified as distinct sub-species 20 and 31, respectively, or as to the thickness of an apical portion of the interconnection member as exemplified in Figure 31, which the Examiner has designated as distinct sub-species 32, or as to the shape of an apical portion of the interconnection member or the cylindrical element as depicted in Figures 33 (Species 34), 35 (Species 36), 34 (Species 35), 36 (Species 37), 37 (Species 38), 38 (Species 39), 39 (Species 40) or 40 (Species 41). Species 40 and 41, Figures 39 and 40, respectively, differ only in the number of interconnecting members 304 between adjacent cylindrical elements, i.e., Figure 39 depicts 4 interconnecting elements between adjacent cylindrical elements 306, while, Figure 40 depicts 2 interconnecting elements 304 between adjacent cylindrical elements 306.

Applicant has conducted a diligent search of the Manual of Patent Classification and has failed to identify any separate patent classifications based upon differences in the opening geometry of the covering metal thin film element or based upon differences in geometries of the structural support element, as claimed. The claims of the present

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application have been classified by the Office as being in Class 623, subclass 1.13. The class and subclass definition for 623/1.13 consists of:

Stent in combination with graft: This subclass is indented under subclass 1.1. Subject matter wherein the artificial blood vessel or part thereof includes an artificial blood vessel support frame and an artificial blood vessel. (1) Note. The term "stent" refers to the artificial blood vessel support frame. (2) Note. The term "graft" refers to the artificial blood vessel.

Applicant submits that Class 623/1.13 is, indeed, the single most appropriate class for the claimed invention as each claim is directed to a combination of a support structure (i.e., an "artificial blood vessel support frame") and a covering (i.e., an "artificial blood vessel"). Certainly, the claims in the application also relate to other subclasses also indented under Class 623/1.1, such as subclass 1.15 (Stent Structure); subclass 1.16 (Stent structure having multiple connected bodies); subclass 1.18 (Stent structure having shape memory); or subclass 1.49 (Artificial vessels made of synthetic material). However, as all of the claims are directed to a "stent in combination with graft" as per Class 623/1.13, the specific dependent claims which further define features of the support structure (e.g., stent) or of the covering (e.g., graft), are merely sub-combinations which have not achieved separate classification in the Manual of Classification or separate status in the art.

Applicant respectfully submits that searching such minor differences between the embodiments of the opening geometries and the support element geometries imposes no undue or extraordinary burden upon the Examiner sufficient to warrant the species and sub-species categorization argued by the Examiner or require restriction under 35 U.S.C. §121. The different geometries of the openings and the different geometries of the structural support members are each generically claimed within the ambit of the presently pending independent claims. The Examiner has made no showing that the different opening geometries or support element geometries have attained separate classification, separate status, or require separate searching of the applicable prior art. Thus, the variations in opening geometry or orientation as depicted in the purported Species 3-23, 42, or variations in support structure geometry as depicted in the purported Species 1-2,

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24-41, have do not constitute separate and distinct inventions or species for which the Examiner's restriction requirement under 35 U.S.C. §111 is proper.

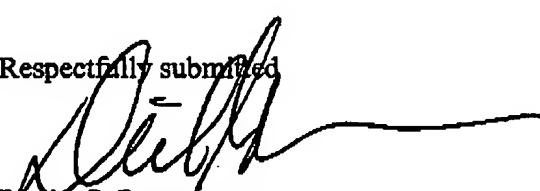
Applicant respectfully solicits the Examiner's favorable reconsideration and withdrawal of the restriction requirement under 35 U.S.C. §111.

This Paper is being concurrently filed with an Amendment Transmittal, which includes a fee calculation sheet and any applicable requests for Extension of Time. Other than those stated in the Amendment Transmittal, no additional fees are believed necessitated by the filing of this Paper. Should any such additional fees be required, the Director is hereby authorized to deduct them from Deposit Account NO. 18-2000, of which the undersigned is an authorized signatory.

Should the Examiner believe that there are any outstanding matters capable of resolution by a telephone interview, the Examiner is encouraged to telephone the undersigned attorney of record.

Applicant requests examination of pending claims 1-35, as amended, and requests that such claims be allowed and pass to issue.

Respectfully submitted



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